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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,639	01/12/2004	John P. Wikswo	14506-44211	1080

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EXAMINER
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BOWERS, NATHAN ANDREW

ART UNIT	PAPER NUMBER
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1797

MAIL DATE	DELIVERY MODE
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10/25/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/755,639	Applicant(s) WIKSWO ET AL.	
	Examiner Nathan A. Bowers	Art Unit 1797	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2007.  
2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-81 is/are pending in the application.  
4a) Of the above claim(s) 25-74 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-24 and 75-81 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- 1) Claims 1-4, 6 and 8-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dodgson (US 20030107386).

With respect to claims 1, 2, 75 and 76, Dodgson discloses a device for monitoring the status of at least one cell. The apparatus comprises a first substrate, a second substrate supported by the first substrate, and a first passage formed within the body of the second substrate. An opening is formed on the first surface of the second substrate such that the first passage is in fluid communication with a reaction area formed above the second substrate. Paragraphs [0009] and [0010] state that electrodes (Figure 3:24,26) are provided to detect the presence of a cell (Figure 3:16) to be tested. A third substrate is positioned above the second substrate to define a reaction area therebetween, and a second passage is formed below the third substrate in fluid communication with the reaction area. This is apparent from Figure 3. Paragraph [0036] clearly states that at least one seal element (Figure 3:22) is positioned on the second substrate and such that it encircles the opening. Another embodiment in Figure 4 depicts a similar apparatus, however, the third substrate is replaced with a sidewall feature. Dodgson does not expressly describe an embodiment in which a third substrate and sidewalls are both formed above the second substrate to define a reaction chamber and a second passage.

Fig.3.

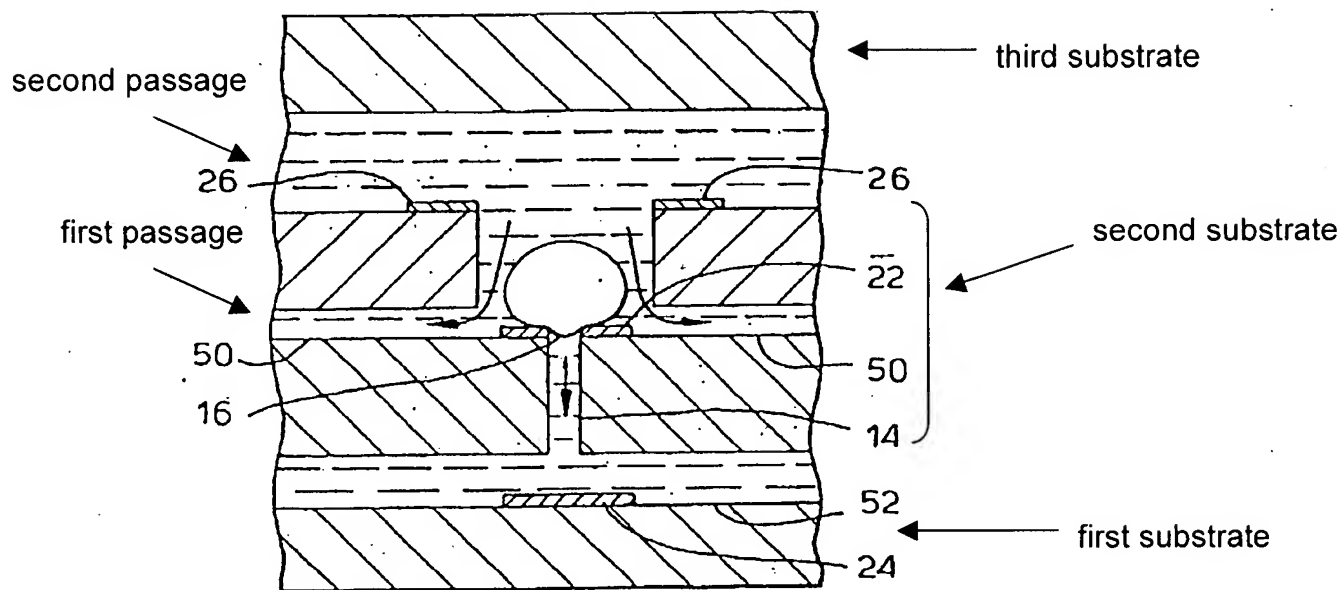
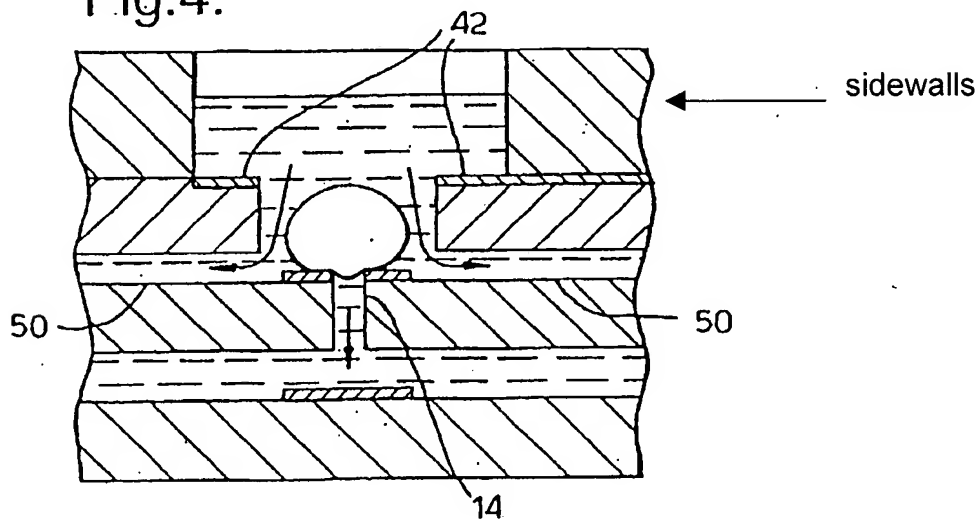


Fig.4.



At the time of the invention, it would have been obvious to alter the construction of Dodgson's device by incorporating features set forth in the embodiments presented in Figures 3 and 4. It would have been apparent to provide a reaction chamber defined by both a third

substrate and sidewalls, as such construction is considered to be well known and commonly practiced in the art. It would require only minor structural alterations to either of the presented embodiments to form a reaction chamber and second passage bound by both a sidewall area and a third substrate.

With respect to claims 3, 4 and 6, Dodgson discloses the apparatus set forth in claim 2 as set forth in the 35 U.S.C. 103 rejection above. In addition, Dodgson states that the electrode sensing elements further act as an electroporation device capable of stimulating cells positioned within the reaction area. This is taught in paragraph [0039]. A medium is introduced to the reaction area through the second passage such that the sensor measures the response of the cell to the medium. Paragraph [004] states that variations in the medium cause a variation in the impedance of the cell in the reaction area.

With respect to claims 8 and 9, Dodgson discloses the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. Dodgson additionally indicates that control devices are provided at the first and second passages to regulate fluid flow. Paragraph [0043] describes the use of valves. Valves are considered to be well known in the art.

With respect to claims 10 and 11, Dodgson discloses the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. Although Dodgson does not expressly disclose the use of reservoirs in communication with the first and second passages, it is understood that the use of reservoirs as supply medium containers and waste containers is notoriously well

known in the art. It would have been obvious to equip the apparatus of Dodgson with reservoirs in order to perfuse a solution through the system in a continuous nature.

With respect to claims 12-15, 17, 19, 21-24 and 78-80, Dodgson discloses the apparatus as previously described above. Dodgson additionally states in paragraphs [0010], [0013] and [0014] that a plurality of chambers are defined by the first, second and third substrates. An array of chambers is formed such that each chamber includes a sensor/poration electrode capable of detecting impedance and electrically stimulating a cell. Each chamber is connected to neighboring chambers via the second passage formed by the third substrate and the sidewalls.

2) Claims 5, 7, 16, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dodgson (US 20030107386) as applied to claims 2 and 12, and further in view of Rubinsky (US 6482619).

Dodgson discloses the apparatus set forth in claims 2 and 12 as set forth in the 35 U.S.C. 103 rejections above, however does not expressly state that fluid moves through the first passage to the cell. Dodgson teaches that fluid moves through the first passage away from the cell (See Figures 3 and 4).

Rubinsky discloses a device for monitoring the status of a least one cell. Rubinsky discloses a substrate (Figure 1:11) comprising a body portion that defines a first passage (Figure 1:13) and an opening (Figure 1:18) in communication with the first passage. Another substrate (Figure 1:17) further defines a chamber and a second passage (Figure 1:16) formed between the substrates. This is disclosed in column 17, lines 11-27. Rubinsky teaches in column 17, lines

28-42 that the first and second passages each carry a fluid medium to a cell at the opening in order to determine the response of the cell to each medium.

Dodgson and Rubinsky are analogous art because they are from the same field of endeavor regarding cell monitoring systems.

At the time of the invention, it would have been obvious to alter the apparatus of Dodgson in order to allow the addition of fluids to both the first and second passages. It would have been beneficial to add fluids to the reaction chamber via the first and second passages because this would have allowed one to simultaneously test the effects of multiple compounds on analytes within the chamber.

3) Claims 77 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dodgson (US 20030107386) as applied to claims 1 and 12, and further in view of Wang (US 20020182627).

Dodgson discloses the apparatus set forth in claims 1 and 12 as set forth in the 35 U.S.C. 103 rejections above. Dodgson teaches that the body portion of the second substrate further defines an intersection portion where the first passage and the opening on the first surface of the second substrate are in fluid communication. Dodgson, however, does not expressly state that the intersection is partially formed as a cone shaped portion.

Wang discloses a device for monitoring the status of at least one cell. Wang discloses the use of a substrate (Figure 2:10) that includes an opening (Figure 2:12) used to link first and second fluid passages. From Figure 2, it is apparent that this intersection point is at least partially formed as a cone shaped portion (Figures 2B-2E).



Dodgson and Wang are analogous art because they are from the same field of endeavor regarding cell monitoring systems.

At the time of the invention, it would have been obvious to alter the apparatus of Dodgson to ensure that a portion of the second substrate was formed in the shape of a cone. Cone shapes serve to funnel cells towards the opening where they then form a seal. Mere changes in shape are generally not sufficient to distinguish over the prior art when the changes in shape do not produce a distinctly different mode of operation. See MPEP 2144.04.

#### ***Response to Arguments***

Applicant's arguments filed 29 August 2007, with respect to the 35 U.S.C. 102 rejections involving Anderson have been fully considered and are persuasive. These rejections have been withdrawn.

Applicant's arguments filed 29 August 2007 with respect to the 35 U.S.C. 103 rejections involving Dodgson have been fully considered but they are not persuasive.

*Applicant's principle arguments are*

*(a) Dodgson does not disclose the use of a seal element positioned on the second substrate proximate to the opening.*

In response to Applicant's arguments, please consider the following comments.

The material layers (Figure 3:22) positioned around the opening are considered to be seal elements. Paragraph [0036] states that these material layers are used to achieve a very high

resistance seal between the channels immediately above and below the opening when the opening is occupied by a cell.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

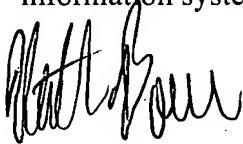
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

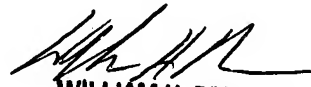
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



NAB

  
**WILLIAM H. BEISNER**  
**PRIMARY EXAMINER**  
**GROUP 1797**